IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
JACKSON DIVISION

Melissa Mitchell,	)
	)
Plaintiff,	) Case No. 1:16-cv-2384-JDB-egb
	)
vs.	)
	) SECOND AMENDED COMPLAINT
	) AND JURY DEMAND
BOEHRINGER INGELHEIM	)
PHARMACEUTICALS, INC.,	)
	)
Defendant.	)

Plaintiff Melissa Mitchell, ("Plaintiff"), by and through undersigned counsel, brings this action seeking judgment against Boehringer Ingelheim Pharmaceuticals, Inc. ("Defendant") for injuries and damages caused by Plaintiff's ingestion of JARDIANCE, a type 2 diabetes drug in the *gliflozin* class.

INTRODUCTION

1. Defendant, directly or through its agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold JARDIANCE for the treatment of diabetes.

2. Defendant concealed, and continues to conceal, its knowledge of JARDIANCE's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

3. As a result of the defective nature of JARDIANCE, persons who were prescribed and ingested JARDIANCE, including Plaintiff, have suffered and may continue to suffer severe personal injuries, including but not limited to diabetic ketoacidosis.

4. After beginning treatment with JARDIANCE, and as a direct and proximate result of Defendant's actions and inaction, Plaintiff developed diabetic ketoacidosis ("DKA"). Plaintiff's

ingestion of the defective and unreasonably dangerous drug has caused and will continue to cause injury and damage to Plaintiff.

5. This is an action for product liability, failure to warn, strict liability, and negligence against BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

6. Plaintiff brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting JARDIANCE, including but not limited to development of DKA. Plaintiff accordingly seeks compensatory damages, monetary restitution, and all other available remedies as a result of injuries caused by her ingestion of JARDIANCE.

PARTIES

7. At all times relevant hereto, Plaintiff Melissa Mitchell was a resident and citizen of Selmer, Tennessee, located in McNairy County, and was prescribed, purchased, ingested, and exposed to JARDIANCE in McNairy County, Tennessee. As a result of ingesting JARDIANCE, Plaintiff suffered personal and economic injuries, which developed and occurred in McNairy County, Tennessee, and Plaintiff sought treatment for the effects attendant thereto.

8. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIP") is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, CT 06877. BIP is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug JARDIANCE.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 USC § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and

because Defendant is incorporated and has its principal place of business in states other than the state in which Plaintiff is a resident and citizen.

10. At all times relevant to this action, Defendant engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including JARDIANCE, within the State of Tennessee, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

11. At all times relevant to this action, Defendant waswas engaged in disseminating inaccurate, false, and misleading information about JARDIANCE to consumers, including Plaintiff, and to health care professionals in the State of Tennessee, with a reasonable expectation that such information would be used and relied upon by consumers and health care professionals throughout the State of Tennessee.

12. Defendant engaged in substantial business activities in the State of Tennessee. At all relevant times, Defendant transacted, solicited, and conducted business in Tennessee through its employees, agents, and/or sales representatives and derived substantial revenue from such business in Tennessee.

13. Further, Defendant committed torts in whole or in part against Plaintiff in the State of Tennessee. As such, this Court has personal jurisdiction over Defendant.

14. Venue of this case is proper in the Western District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) because Plaintiff at all times relevant was and is a resident of this District and was injured in this District, and because a substantial part of the events giving rise to the claim occurred in this District.

FACTUAL BACKGROUND

15. On August 1, 2014, the FDA approved JARDIANCE (empagliflozin) for use in treatment of type 2 diabetics. JARDIANCE is a part of the *gliflozin* drug class, and was one of the first *gliflozins* approved for use in the United States. The *gliflozin* class is referred to generally as SGLT2 (Sodium Glucose Cotransporter 2) inhibitors.

16. SGLT2 inhibitors, including JARDIANCE, are indicated only for lowering blood glucose in type 2 diabetics.

17. SGLT2 inhibitors, including JARDIANCE, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

18. Defendant is responsible for designing, developing, manufacturing, marketing, distributing, selling and otherwise introducing JARDIANCE into the stream of commerce.

19. Though JARDIANCE is indicated for only improved glycemic control in type 2 adult diabetics, Defendant has marketed and continue to market JARDIANCE for off label purposes, including but not limited to weight loss and reduced blood pressure.

20. Since JARDIANCE's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of these drugs.

21. An analysis of the FDA adverse event database shows that patients taking one of the SGLT2 inhibitors, including JARDIANCE, are several times more likely to report ketoacidosis and/or severe kidney damage than those taking non-SGLT2 diabetes drugs to treat diabetes.

22. Despite Defendant's knowledge of the increased risk of severe injury among users of JARDIANCE, they did not warn patients but instead continued to defend JARDIANCE, mislead physicians and the public, and minimize unfavorable findings.

23. Consumers, including Plaintiff, who have used JARDIANCE for treatment of diabetes, have several alternative safer products available to treat the conditions, including metformin, Diabinese, Amaryl, or Glucotrol.

24. Defendant knew of the significant risk of diabetic ketoacidosis caused by ingestion of JARDIANCE. However, Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity of such risks.

25. To the contrary, Defendant conducted nationwide sales and marketing campaigns to promote JARDIANCE, and they willfully deceived Plaintiff, Plaintiff's health care professionals, the medical community, and the general public as to the health risks and consequences of the use of JARDIANCE.

26. As a direct result of Defendant's above described conduct, in or about February 2015, Plaintiff was prescribed and began taking JARDIANCE to treat diabetes.

27. Plaintiff ingested and used JARDIANCE as prescribed and in a foreseeable manner.

28. The JARDIANCE used by Plaintiff was provided in a condition substantially the same as the condition in which it was manufactured and sold.

29. Plaintiff agreed to initiate treatment with JARDIANCE in an effort to reduce her blood sugar. In doing so, Plaintiff relied on claims made by Defendant that JARDIANCE was safe and effective for the treatment of diabetes.

30. Instead, JARDIANCE can cause severe injuries, including diabetic ketoacidosis.

31. After beginning treatment with JARDIANCE, and as a direct and proximate result thereof, Plaintiff suffered diabetic ketoacidosis, or DKA, on or about June 2, 2015.

32. As a result of her development of DKA due to consuming JARDIANCE, Plaintiff was hospitalized until on or about June 5, 2015.

33. Plaintiff used JARDIANCE consistently as prescribed from the date she was prescribed the drug until she suffered her injury on June 2, 2015.

34. Defendant knew or should have known the risks associated with using JARDIANCE, including the risk of developing diabetic ketoacidosis.

35. While Defendant did not warn about the risks of DKA, on May 15, 2015, the FDA issued a safety alert covering the SGLT-2 inhibitor class, warning about the risk of DKA and advising that the FDA would continue to evaluate the safety issue.

36. The data used in FDA's May 15, 2015 safety alert was collected from March 2013 to June 6, 2014, nearly two months prior to Jardiance's approval.

37. The data FDA used to issue its May 15, 2015 safety alert came from the FDA Adverse Event Reporting System ("FAERS"), a publicly available database which Defendant, as a manufacturer of a pharmaceutical drug under consideration for an NDA approval by the FDA, is supposed to monitor for signals that the drug might be unsafe. The same kinds of signals that led FDA to issue its alert.

38. As part of its continued evaluation, on December 4, 2015 the FDA issued a new safety communication disclosing they had found 73 adverse events reported between March 2013 and May 2015 that required hospitalization due to ketoacidosis related to SGLT-2 inhibitors. The

FDA noted adverse event reports "include only reports submitted to FDA, so there are likely additional cases about which we are unaware."

39. In light of the data disclosed in the December 4, 2015 safety communication, the FDA changed the label for JARDIANCE and the other SGLT-2 inhibitors to include a warning "about the risks of too much acid in the blood" and urged patients taking SGLT-2 inhibitors to stop taking the drug and seek immediate medical attention if they have any symptoms of ketoacidosis.

40. As part of its December 4, 2015 Safety Communication and label change, the FDA further required all manufacturers of SGLT-2 inhibitors, including Defendant, to conduct a postmarketing study wherein the manufacturers would analyze spontaneous postmarketing reports of ketoacidosis in patients treated with SGLT-2 inhibitors, including specialized follow-up to collect additional information, over a 5-year period.

41. Until the FDA required Defendant to change the JARDIANCE label in December 2015, Defendant did not warn about JARDIANCE causing DKA. In fact, until December 2015 the JARDIANCE label did not contain any information about ketoacidosis, ketones, acidosis, DKA, or any information related to DKA on its label whatsoever.

42. FDA got the information used in its May 15, 2015 safety alert from data collected from the FDA Adverse Event Reporting System ("FAERS") database between March 2013 and June 6, 2014.

43. JARDIANCE was not approved until August 1, 2014.

44. FDA guidelines for good pharmacovigilance practices require manufacturers to monitor the available data related to adverse events in the drug class, and specifically reference monitoring the FAERS database. "Additional cases could be identified from the sponsor's global

adverse event databases, the published literature, and other available databases, such as FDA's Adverse Event Reporting System (AERS)[.]"[1]

45. "The manufacturer of a pharmaceutical drug such as JARDIANCE bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009).

46. The Code of Federal Regulations ("CFR's") require manufacturers to alert FDA of potential risks and unequivocally place responsibility of monitoring the information to be included in the label at the manufacturer's doorstep. *See e.g.*, 21 CFR § 201.80(e) requires a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."; 21 CFR § 314.80(b) places responsibility for postmarketing surveillance on the manufacturer; and 73 Fed.Reg. 49605 says, "Manufacturers continue to have a responsibility under Federal law ... to maintain their labeling and update the labeling with new safety information."

47. The entire set of information used by the FDA to issue its May 15, 2015 alert about SGLT-2 inhibitors causing elevated levels of acid in the blood was available to Defendant prior to approval of JARDIANCE.

48. The FDA, like all regulatory agencies, tracks adverse event data in FDA Adverse Event Reporting System ("FAERS").

[1] *FDA Guidance for Industry Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*, p. 9, Final Version March 1, 2005, draft published May 4, 2004, available online at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf (last accessed January 31, 2017).

49. The FAERS database established a clear signal that patients taking one of the SGLT-2 inhibitors, including JARDIANCE, are several times more likely to report ketoacidosis than those taking non-SGLT-2 diabetes drugs to treat diabetes.

50. For nearly a year and a half prior to JARDIANCE's release, FDA received a significant number of reports of DKA among users of SGLT-2 inhibitors, including JARDIANCE.

51. In fact, the FAER's data establishing a signal between DKA and SGLT-2 inhibitor use, the same data which led FDA to issue its first warning about SGLT-2 inhibitors causing DKA, stemmed from reports provided *before* JARDIANCE entered the market.

52. The FAER's database is public and available to pharmaceutical manufacturers, meaning BIP should have been aware of the signal prior to its decision to release JARDIANCE.

53. Even though the same information FDA relied on to issue its May 15, 2015 warning was available to them before JARDIANCE was approved, Defendant did not warn about the risks of DKA.

54. JARDIANCE's warnings were defective and/or unreasonably dangerous with regard to the increased risk of exposure to DKA.

55. The warnings were defective and/or unreasonably dangerous in that there simply were no warnings for DKA in the label for JARDIANCE at any time prior to Plaintiff's injury on June 2, 2015, despite information being available to Defendant prior to approval of JARDIANCE that linked JARDIANCE to significantly increasing the risk of causing DKA in users of the drug.

56. There was no DKA warning at any time prior to FDA requiring the December 4, 2015 label change.

57. DKA is a condition most commonly found in type 1 diabetics. DKA in type 2 diabetics such as Plaintiff is atypical.

58. In 2015, multiple published case reports identified additional DKA events in patients treated with SGLT-2s. These reports include:

a. Hall, *Hall - 2015 -Case report of Ketoacidosis associated with Canagliflozin (Invokana).pdf*, March 5-8 ENDO CONFERENCE(2015).

b. Tomohide Hayami et al., *Case of ketoacidosis by a sodium-glucose cotransporter 2 inhibitor in a diabetic patient with a low-carbohydrate diet*, JOURNAL OF DIABETES INVESTIGATION n/a–n/a (2015).

c. Julia Hine et al., *SGLT inhibition and euglycaemic diabetic ketoacidosis*, THE LANCET DIABETES & ENDOCRINOLOGY (2015).

d. Nobuya Inagaki et al., *Efficacy and safety of canagliflozin alone or as add-on to other oral antihyperglycemic drugs in Japanese patients with type 2 diabetes: A 52-week open-label study*, 6 JOURNAL OF DIABETES INVESTIGATION 210–218 (2015).

e. Anne L. Peters et al., *Euglycemic Diabetic Ketoacidosis: A Potential Complication of Treatment With Sodium-Glucose Cotransporter 2 Inhibition*, DIABETES CARE dc150843 (2015).

f. Reginald St. Hilaire & Heather Costello, *Prescriber beware: report of adverse effect of sodium-glucose cotransporter 2 inhibitor use in a patient with contraindication*, 33 THE AMERICAN JOURNAL OF EMERGENCY MEDICINE 604.e3–604.e4 (2015).

59. The development of Plaintiff's injuries was preventable and resulted directly from Defendant's failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of JARDIANCE. Both Defendant's conduct and the product defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff's injuries.

60. Plaintiff's injuries were a reasonably foreseeable consequence of Defendant's conduct and JARDIANCE's defects.

61. At all times material hereto, Defendant, by and through its agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold JARDIANCE without adequate instructions or warning of serious side effects and unreasonably dangerous risks.

62. Plaintiff would not have used JARDIANCE had Defendant properly disclosed the risks associated with its drug. Thus, had Defendant properly disclosed the risks of developing DKA associated with JARDIANCE, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting those medications.

63. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with taking JARDIANCE.

64. As a result of Defendant's actions, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations, both separately and collectively.

65. As a direct and proximate result of Defendant's negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of JARDIANCE, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual and compensatory damages from Defendant.

66. There is no consensus as to the mechanism of action for how JARDIANCE and other SGLT-2 inhibitors cause DKA. However, there are several different ways identified in recent studies that scientists have speculated that JARDIANCE might cause DKA. including

a. SGLT2 is expressed in pancreatic α-cells, and SGLT2 inhibitors promote glucagon secretion;

b. phlorizin, a nonselective inhibitor of SGLT family transporters decreases urinary excretion of ketone bodies; and/or,

c. a decrease in the renal clearance of ketone bodies could also increase the plasma ketone body levels.[2]

67. The warning in the JARDIANCE label regarding DKA was inadequate, in that there was no warning at all in the label from the time JARDIANCE was approved by FDA, to the time Plaintiff first used JARDIANCE, and through the date of Plaintiff's injury on June 2, 2015.

68. JARDIANCE was unreasonably dangerous at the time of its release in that:

a. prior to approval and release of JARDIANCE, FDA's FAER's database established a signal between SGLT-2 inhibitors and DKA;

b. from 2013 through the release of JARDIANCE, FDA identified at least 20 cases of DKA;

c. armed with this data, Defendant did nothing to amend the label or utilize the CBE process; and,

d. through review of this data that was only available at the time of JARDIANCE's release, SGLT-2 inhibitors can cause DKA – an injury that almost never occurs in the type 2 diabetic population.

[2] Taylor, S. I., Blau, J. E., & Rother, K. I. (2015). SGLT2 Inhibitors May Predispose to Ketoacidosis. *The Journal of Clinical Endocrinology and Metabolism*, *100*(8), 2849–2852. http://doi.org/10.1210/jc.2015-1884

69. Plaintiff has suffered from mental anguish from the knowledge that life-long complications may result from the injuries caused by JARDIANCE.

COUNT I
PRODUCTS LIABILITY – BREACH OF OR FAILURE TO DISCHARGE A DUTY TO WARN - STRICT LIABILITY (under Tenn. Code § 29-28-102(6))

70. Plaintiff restates the allegations set forth above as if fully rewritten herein.

71. Defendant has engaged in the business of developing, researching, testing, licensing, packaging, labeling, promoting, marketing, selling, and/or distributing JARDIANCE. Through that conduct, Defendant knowingly and intentionally placed JARDIANCE into the stream of commerce with full knowledge that it would reach consumers, such as Plaintiff, who ingest it.

72. Defendant researched, developed, tested, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released JARDIANCE into the stream of commerce. In the course of same, Defendant directly advertised, marketed, and promoted JARDIANCE to health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of JARDIANCE.

73. Defendant expected JARDIANCE to reach, and they did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendant.

74. JARDIANCE, as manufactured and/or supplied by Defendant, was defective due to inadequate warnings or instructions, in that the label contained no warning regarding DKA whatsoever. Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers as alleged herein, including but not limited to the risk of diabetic

ketoacidosis, and they failed to adequately warn consumers and/or their health care professionals of such risks.

75. JARDIANCE was defective and unsafe such that it was unreasonably dangerous when it left Defendant's possession and/or control, was distributed by Defendant, and ingested by Plaintiff. JARDIANCE contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with JARDIANCE, including the development of Plaintiff's diabetic ketoacidosis.

76. This defect caused serious injury to Plaintiff, who used JARDIANCE for its intended purpose and in a reasonably anticipated manner.

77. At all times herein mentioned, Defendant had a duty to properly test, develop, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure JARDIANCE did not cause users to suffer from unreasonable and dangerous risks.

78. Defendant negligently and recklessly labeled, distributed, and promoted JARDIANCE.

79. Defendant had a continuing duty to warn Plaintiff of the dangers associated with JARDIANCE.

80. Defendant, as a manufacturer, seller, or distributor of prescription drugs, is held to the knowledge of an expert in the field.

81. Plaintiff could not have discovered any defects in JARDIANCE through the exercise of reasonable care, and instead, Plaintiff relied upon the skill, superior knowledge, and judgment of Defendant.

82. Defendant was aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendant knew or should have known that JARDIANCE caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of JARDIANCE, as referenced above, were known to Defendant, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

83. JARDIANCE, as manufactured and/or supplied by Defendant, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

84. Defendant knew or should have known that the limited warnings disseminated with JARDIANCE was inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drugs. In particular, Defendant failed to communicate warnings and instructions to doctors that were appropriate and adequate to render its products safe for ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the products for treatment of diabetes.

85. Defendant communicated information to health care professionals that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drugs safely for use by patients for the purposes for which they are intended. In particular, Defendant:

a. at all relevant times, provided no warning that JARDIANCE could cause DKA, despite the fact that Defendant knew or should have known JARDIANCE causes DKA;

b. disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of JARDIANCE;

b. continued to aggressively promote JARDIANCE even after Defendant knew or should have known of the unreasonable risks from use;

c. failed to accompany its product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of JARDIANCE and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of JARDIANCE's effect on renal function and propensity to cause ketoacidosis;

e. failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment; and;

f. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of JARDIANCE.

86. To this day, Defendant has failed to adequately and accurately warn of the true risks of injuries associated with the use of JARDIANCE.

87. Due to these deficiencies and inadequacies, JARDIANCE was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by Defendant, respectively.

88. Had Defendant properly disclosed and disseminated the risks associated with JARDIANCE, Plaintiff would have avoided the risk of developing injuries as alleged herein.

89. Defendant is liable to Plaintiff for injuries caused by its negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of JARDIANCE and the risks associated with its use.

90. As a foreseeable, direct, and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications.

91. In addition, as a result of the injuries caused by Defendant, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT II
NEGLIGENCE (under Tenn. Code § 29-28-102(6))

92. Plaintiff restates the allegations set forth above as if fully rewritten herein.

93. Defendant directly or indirectly caused JARDIANCE, to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

94. Defendant owed Plaintiff and other consumers a duty to exercise reasonable care when marketing, advertising, distributing, and selling JARDIANCE, including the duty to take all reasonable steps necessary to ensure its drug was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with JARDIANCE.

95. At all times material hereto, Defendant had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of JARDIANCE.

96. Defendant had a duty to disclose to health care professionals the causal relationship or association of JARDIANCE to the development of Plaintiff's injuries.

97. Defendant's duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of JARDIANCE, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of JARDIANCE, including the injuries suffered by Plaintiff.

98. During the time that Defendant packaged, labeled, promoted, distributed, and/or sold JARDIANCE, they knew, or in the exercise of reasonable care should have known, that JARDIANCE was defective, dangerous, and otherwise harmful to Plaintiff.

99. Defendant knew, or in the exercise of reasonable care should have known, that the use of JARDIANCE could cause or be associated with Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

100. Defendant knew that many health care professionals were prescribing JARDIANCE, and that many patients developed serious side effects including but not limited to diabetic ketoacidosis.

101. Defendant breached its duty of reasonable care and failed to exercise ordinary care in the research, development, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of JARDIANCE in interstate commerce, in that Defendant knew and had reason to know that a consumer's use and ingestion of JARDIANCE created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

102. Defendant failed to exercise due care under the circumstances, and its negligence includes the following acts and omissions:

a. failing to properly and thoroughly test JARDIANCE before releasing the drugs to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of JARDIANCE;

c. failing to conduct sufficient post-market testing and surveillance of JARDIANCE;

d. marketing, advertising, distributing, and selling JARDIANCE to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the medication and without proper instructions to avoid foreseeable harm;

e. failing to accompany its product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of JARDIANCE and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of JARDIANCE's effect on acid balance and renal function;

g. failing to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment;

h. failing to exercise due care when advertising and promoting JARDIANCE; and

i. negligently continuing to manufacture, market, advertise, and distribute JARDIANCE after they knew or should have known of its adverse effects.

103. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, common, and intended use.

104. Defendant knew and/or should have known that consumers such as Plaintiff would suffer injuries such as DKA as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of JARDIANCE.

105. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of JARDIANCE because Defendant provided no warning at all about DKA.

106. Defendant's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

107. Defendant's conduct, as described above, was reckless. Defendant's actions and inaction risked the lives of consumers and users of its product, including Plaintiff.

108. Defendant's JARDIANCE was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant.

109. At all times relevant hereto, JARDIANCE was marketed and labeled in an unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular by Plaintiff.

110. Plaintiff used JARDIANCE for its intended purposes and in a manner normally intended: to treat diabetes.

111. The harm caused by JARDIANCE far outweighed the benefits, rendering JARDIANCE more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products.

112. Plaintiff could not, in the reasonable exercise of care, have discovered the defects of JARDIANCE and perceived the danger.

113. The defects in the labeling and marketing of JARDIANCE were substantial contributing factors in causing Plaintiff's injuries. But for Defendant's acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

114. As a foreseeable, direct, and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications.

115. In addition, as a result of the injuries caused by Defendant, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against the Defendant, and each of them, individually, jointly, and severally, as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering;

4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;

5. Prejudgment interest at the highest lawful rate allowed by law;

6. Interest on the judgment at the highest legal rate from the date of judgment until collected;

7. Attorneys' fees, expenses, and costs of this action; and

8. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff demands trial by jury on all issues within this Petition.

Dated: February 3, 2017

Respectfully submitted,

JOHNSON BECKER, PLLC

s/Rolf T. Fiebiger

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically this the 3rd day of February, 2017. This filing was served via the Court's Electronic Case Filing System to all parties and counsel indicated on the electronic filing receipt. Copies may also be accessed through the Court's electronic case filing system.

s/Rolf T. Fiebiger
Rolf T. Fiebiger